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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/061,438	MCCROSKEY ET AL.	
	Examiner	Art Unit	
	David J Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *22-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, drawn to a method, classified in class 435, subclass 7.9, for example.

II. Claims 22-34, drawn to a method, classified in class 435, subclass 7.1, for example.

III. Claims 35-40, drawn to devices and kit, classified in class 422, subclass 70, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention I requires the step of measuring a selected property of a protein, while Invention II requires measuring a property of a labeling agent.

Inventions (I or II) and III are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in a materially different process, such as a process for characterizing the binding affinity of lectins.

Because these inventions are distinct for the reasons given above and the search required for each group is not required for the other group, restriction for examination purposes as indicated is proper.

During a telephone conversation with Attorney Suzanne Biggs on September 29, 2004, a provisional election was made with traverse to prosecute the Invention I, claims 1-21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 6, and 12, the claim preambles do not correspond to the outcomes of each method. For example, the preamble in each claim recites a method of quantitation of glycated protein, while the final step (f) in each claim recites the step of calculating the percentage of glycated protein. It appears that the step of quantitating glycated protein is completed in step (e) in each of the claims. The purpose of extraneous step (f) in each claim is not clear.

In step (a) of claims 1, 6, 12, and 16-17 the recitation of "a negatively charged group" is indefinite. The identity of such a "negatively charged group" or to which entity(s) said group is attached is not clear. In addition, it is not clear under what conditions said group is negatively charged, as well as its purpose in the overall method.

In step (b) of claims 1 and 6, the recitation of "unbound protein" lacks antecedent basis and is indefinite because the identity of said "unbound protein" is not clear. In step (b) of claim 1, it is not clear whether said "unbound protein" is the same protein as one or both of the subsequently recited glycated protein and/or non-glycated protein. In step (b) of claim 6, it is not clear whether said "unbound protein" is the same protein as the previously recited glycated protein.

In step (b) of claims 1 and 6, the recitation of "sufficient" is indefinite because it is not clear what noun is being modified by "sufficient." It is also not clear what property or characteristic of "an aliquot" and/or "a first buffer" causes said "aliquot" and/or "first buffer" to be sufficient, as well as the standard or degree of sufficiency required by "sufficient."

In step (b) of claim 1, the recitation of "non-glycated protein" lacks antecedent basis.

In step (b) of claim 1, it is not clear under what mechanism the glycated protein and non-glycated protein bind to the solid support matrix. Because Applicants have not recited a mechanism by which glycated protein and non-glycated protein bind to the solid support matrix, it is not clear how pH is related to the ability of glycated protein and non-glycated protein to bind to the solid support matrix. The recitation of "said first buffer has a pH selected to allow both glycated and non-glycated protein to be bound to said solid support matrix" is indefinite because

Applicants have not recited sufficient causal relationship between the composition of the solid support matrix, the composition of each binding protein, and buffer pH.

In step (b) of claim 1, the recitation of "to be bound" is indefinite because it is not clear what verb tense is intended or whether the term "bound" is being used as a verb or as an adjective meaning "intending to go." As a result, it is not clear whether this step requires actual binding between protein and matrix.

In step (c) of claim 1 and 6, the recitation of "protein", "said protein", or "bound protein reading" is indefinite. In step (c) of claim 1, it is not clear whether Applicants are referring to the aforementioned glycated protein, non-glycated protein, or both proteins. In step (c) of claim 6, the recitation of "bound protein" lacks antecedent basis.

In step (d) of claims 1 and 6, the recitation of "unbound protein" is indefinite because the identity of said "unbound protein" is not clear. In step (d) of claim 1, it is not clear whether said "unbound protein" is the same protein as one or more of the previously recited glycated protein, non-glycated protein, and/or unbound protein. Assuming that the "unbound protein" recited in step (d) of claims 1 and 6 is the same type of "unbound protein" recited in step (b), it is not clear why it is necessary to repeat this rinsing step twice.

In step (d) of claim 1, the recitation of "said second buffer has a pH selected to allow glycated protein to be bound to said solid support matrix but where non-glycated protein is not substantially bound to said solid support matrix" is indefinite because Applicants have not recited sufficient causal relationship between the composition of the solid support matrix, the

composition of each binding protein, and buffer pH. It is not clear under what mechanism the glycated protein and non-glycated protein bind to the solid support matrix. Because Applicants have not recited a mechanism by which glycated protein and non-glycated protein bind to the solid support matrix, it is not clear how pH is related to the ability of glycated protein and non-glycated protein to bind to the solid support matrix.

In step (d) of claim 1, the recitation of "to be bound" is indefinite because it is not clear what verb tense is intended or whether the term "bound" is being used as a verb or as an adjective meaning "intending to go." As a result, it is not clear whether this step requires actual binding between protein and matrix.

In step (e) of claims 1 and 6, the recitation of "protein" and "second bound protein reading" is indefinite because the identity of "protein" is not known. In step (e) of claim 1, it is not clear whether Applicants are referring to the aforementioned glycated protein, non-glycated protein, or both proteins. In step (e) of claim 6, the recitation of "bound protein" lacks antecedent basis.

In claim 7, the recitation of "same property" is indefinite because the identity of "property" lacks antecedent basis, as well as the standard or degree of similarity required by "same."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Dean et al. (US 4,269,605).

Dean et al. teach a method of quantitation of glycated protein comprising the steps of: contacting a solid support matrix (see col. 3, lines 29-36) which comprises a negatively charged group (see col. 3, lines 57-60, col. 4, line 11, "polymeric matrix activation", "COOH groups") and a hydroxyboryl compound (see col. 3, lines 37-41) and which has a measurement area (see col. 4, lines 64-67, "dipstick"), with an aliquot of biological sample (see Example 1, "human lysed blood"), contacting said solid support matrix with an aliquot of a first buffer having a pH selected to allow both glycated and non-glycated protein to be bound to said solid support matrix (see col. 5, lines 11-17, "Non-glycoprotein material may be eluted" (noting that, since the phrase "Non-glycoprotein material may be eluted" indicates that both glycoprotein and non-glycoprotein are bound to column, first buffer necessarily has a pH that allows both glycated and non-glycated protein to be bound to said solid support matrix, and would be so recognized by persons of ordinary skill in the art)), quantitating protein bound to said measurement area (see col. 5, lines 35-38, "calculation of % of total protein applied" (noting that "calculation of % of total protein applied" necessarily requires quantitating both glycated and non-glycated protein, and would be so recognized by persons of ordinary skill in the art)), contacting said solid support matrix with an aliquot of a second buffer wherein said second buffer has a pH selected to allow glycated protein to be bound to said solid support matrix where non-glycated protein is not substantially bound to said solid support matrix (see col. 5, lines 11-17, "suitable washing solution", "does not cause the desorption of the specifically bound glycoproteins"), quantitating protein bound to said measurement area (see col. 5, lines 35-38, "Determination of the recovered glycoprotein"), and calculating percentage of glycated protein using said first and

second bound protein readings (see col. 5, lines 35-38, "calculation of % of total protein applied" (noting that "calculation of % of total protein applied" necessarily requires a first bound protein reading quantitating both glycated and non-glycated protein, and a second bound protein reading quantitating glycated protein alone, and would be so recognized by persons of ordinary skill in the art)).

With respect to claims 2-3, Dean et al. teach a method of quantitation of glycated protein wherein the property measured is an absorbance reading (see col. 5, lines 35-38, "absorbance measurements") at a specified wavelength (see col. 6, lines 14-16, "413 nm").

With respect to claim 4, Dean et al. teach a method of quantitation of glycated protein wherein the glycated protein is glycated hemoglobin (see Abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-10 and 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al. (US 4,269,605) in view of Sanders (US 4,407,961) and May & Richards (GB 2206411 A).

Dean et al. teach a method of quantitation of glycated protein as described supra. Dean et al. also teach that the optimum pH for binding glycated protein to a hydroxyboryl compound is between pH 8.0-9.0 (see col. 10, lines 26-29).

Dean et al. do not teach the claimed first buffer pH 5.0-7.9 range for binding glycated and non-glycated protein to a negatively charged anion-exchange matrix.

However, Sanders teaches a buffer having a pH of 6.4-7.2 (see col. 2, line 35) for binding protein to a solid support matrix having a negative charge (see col. 3, lines 31-45, e.g. "carboxy cellulose"). May & Richards teach a method of quantitation of glycated protein using both a negatively charged group and a hydroxyboryl compound (see Abstract).

Therefore, it would have been obvious for a person of ordinary skill in the art to have used the method of quantitation of glycated protein, as taught by Dean et al., with the buffer having a pH of 6.4-7.2, as taught by Sanders, along with the method of quantitation of glycated protein using both a negatively charged group and a hydroxyboryl compound, as taught by May & Richards, because May & Richards teach that a single device with two different binding groups can be used to isolate and quantitate both glycated and non-glycated proteins. Dean et al. teach that hydroxyboryl binding groups have an optimum pH between 8.0-9.0 for binding glycated protein, while Sanders teaches that negatively charged binding groups have an optimum pH between 6.4-7.2 for binding non-glycated proteins.

With respect to claims 7-9, Dean et al. teach a method of quantitation of glycated protein wherein the property measured is an absorbance reading (see col. 5, lines 35-38, "absorbance measurements") at a specified wavelength (see col. 6, lines 14-16, "413 nm").

With respect to claim 10, Dean et al. teach a method of quantitation of glycated protein wherein the glycated protein is glycated hemoglobin (see Abstract).

With respect to claim 12, May & Richards teach solid support having a sample application site (see Fig. 1, element 12, "first binding zone").

With respect to claims 13-15, Dean et al. teach a method of quantitation of glycated protein wherein said dihydroxyboryl compound has an R group consisting of m-aminophenyl (see col. 9, "reactive agent").

With respect to claims 16-19, Sanders teaches a negatively charged solid support matrix (see col. 3, line 44, "carboxy cellulose").

With respect to claim 20, Sanders teaches a method of quantitation of glycated protein using MOPS buffer (see col. 3, line 9).

With respect to claim 21, Sanders teaches a method of quantitation of glycated protein using taurine (see col. 3, line 18-19, "N-2-acetamido-2-aminoethanesulfonic acid").

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al. (US 4,269,605) in view Goldstein et al., 20 Diabetes Care S18 (1997).

Dean et al. teach a method of quantitation of glycated protein as substantially described supra. Dean et al. do not teach the detection of glycated albumin.

However, Goldstein et al. teaches that detection of glycated albumin is a useful test for glycemia in diabetes (see p. S20, col. 2). Therefore, it would have been obvious for a person of ordinary skill in the art to have performed the methods of quantitation of glycated protein, as taught by Dean et al., Sanders, and May & Richards, with glycated albumin, as taught by Goldstein et al., because Goldstein et al. teaches that measurements of glycated albumin correlate well with measurements of glycated hemoglobin, and that measurement of glycated albumin may be advantageous over measurement of glycated hemoglobin in situations where measurement of glycated hemoglobin in not useful.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al. (US 4,269,605) in view of Sanders (US 4,407,961), May & Richards (GB 2206411 A), and Goldstein et al., 20 Diabetes Care S18 (1997).

Dean et al., Sanders, and May & Richards teach methods of quantitation of glycated protein as substantially described supra. Dean et al., Sanders, and May & Richards do not teach the detection of glycated albumin.

However, Goldstein et al. teaches that detection of glycated albumin is a useful test for glycemia in diabetes (see p. S20, col. 2). Therefore, it would have been obvious for a person of ordinary skill in the art to have performed the methods of quantitation of glycated protein, as taught by Dean et al., Sanders, and May & Richards, with glycated albumin, as taught by Goldstein et al., because Goldstein et al. teaches that measurements of glycated albumin correlate well with measurements of glycated hemoglobin, and that measurement of glycated albumin may be advantageous over measurement of glycated hemoglobin in situations where measurement of glycated hemoglobin in not useful.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/062,281 in view of Dean et al. (US 4,269,605) and Sanders (US 4,407,961).

Claims 1-5 recite a method for quantitation of glycated hemoglobin in a biological sample as substantially described supra.

Claims 1-5 do not recite the claimed first buffer pH 5.0-7.0 range for binding glycated and non-glycated protein to a negatively charged anion-exchange matrix. Claims 1-5 also do not recite the claimed second buffer pH 8.0-10.0 range for binding glycated protein to a hydroxyboryl compound.

However, Dean et al. teach that the optimum pH for binding glycated protein to a hydroxyboryl compound is between pH 8.0-9.0 (see col. 10, lines 26-29), while Sanders teaches a buffer having a pH of 6.4-7.2 (see col. 2, line 35) for binding protein to a solid support matrix having a negative charge (see col. 3, lines 31-45, e.g. "carboxy cellulose").

Therefore, it would have been obvious for a person of ordinary skill in the art to have used the method of quantitation of glycated protein, as recited in claims 1-5, with the buffer having a pH of 8.0-9.0, as taught by Dean et al., along with the buffer having a pH of 6.4-7.2, as taught by Sanders, because Dean et al. teach that hydroxyboryl binding groups have an optimum pH

between 8.0-9.0 for binding glycated protein, while Sanders teaches that negatively charged binding groups have an optimum pH between 6.4-7.2 for binding non-glycated proteins.

With respect to claims 6-21, a person of ordinary skill in the art would have recognized that the limitations of claims 6-21 would encompass the broader limitations of claims 1-10 of copending Application No. 10/062,281

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

djv

LONG V. LE
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10/01/04